

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Havenga et al.

**Serial No.:** To be assigned

**Filed:** February 17, 2004

**For:** GENE DELIVERY VECTORS WITH  
CELL TYPE SPECIFICITY FOR PRIMARY  
HUMAN CHONDROCYTES

**Examiner:** To be assigned

**Group Art Unit:** To be assigned

**Attorney Docket No.:** 2578-4509.2US

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: EV326919575US

Date of Deposit with USPS: February 17, 2004

Person making Deposit: Christopher Haughton

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US - 6,445,314 B1	09-2002	Wickham et al.
#US - 5,846,782	12-1998	Wickham et al.
#US - 6,315,992 B1	11-2001	Noh et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO 00/52186	9/8/2000	Introgene B.V.
#WO 00/03029	1/20/2000	Introgene B.V.

Other Documents

#VERMA, Nature, 1997, pp. 239-42, Vol. 389.  
#ANDERSON et al., Nature, 1998, pp. 25-30, Vol. 392.  
#ARAI et al., J. Rheumatol, 1997, pp. 1787-95, Vol. 24.  
#DOHERTY et al., Osteoarthritis and Cartilage, 1998, pp. 153-60, Vol. 6.  
#IKEDA et al., The Journal of Rheumatology, 2000, pp. 990-6, Vol. 27.  
#NIXON et al., Clinical Orthopaedics and Related Research, 2000, pp. S201-213, Vol. 379S.

#ARAI et al., Adenovirus Vector-Mediated Gene Transduction to Chondrocytes: In Vitro Evaluation of Therapeutic Efficacy of Transforming Growth Factor-beta1 and Heat Shock Protein 70 Gene Transduction, Journal of Rheumatology, 1997, pp. 1787-95, Vol. 24, No. 9.

#ARAI et al., Control of Delivered Gene Expression in Chondrocytes Using Heat Shock Protein 70B Promoter, Journal of Rheumatology, August 1999, pp. 1769-74, Vol. 26, No. 8.

#BARAGI et al., Transplantation of Transduced Chondrocytes Protects Articular Cartilage from Interleukin 1-Induced Extracellular Matrix Degradation, Journal of Clinical Investigation, 1995, pp. 2454-60, Vol. 96, No. 5.

#DUPREZ et al., Overexpression of BMP-2 and BMP-4 alters the size and shape of developing skeletal elements in the chick limb, Mechanisms of Development, 1996, pp. 145-57, Vol. 57, No. 2.

#SMITH et al., Genetic Enhancement of Matrix Synthesis By Articular Chondrocytes, Arthritis and Rheumatism, May 2000, pp. 1156-64, Vol. 43, No. 5.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/928,262

Filed: August 10, 2001

For: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY FOR PRIMARY HUMAN CHONDROCYTES, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 2578-4075US  
Serial No.: 09/332,803  
Filing Date: 6/14/1999  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT  
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-4123.2US  
Serial No.: 09/348,354  
Filing Date: 7/7/1999  
Title: CHIMAERIC ADENOVIRUSES

Attorney Docket No.: 2578-4192.1US  
Serial No.: 09/657,492  
Filing Date: 9/8/2000  
Title: MODIFIED ADENOVIRAL VECTORS FOR USE IN GENE  
THERAPY

Attorney Docket No.: 2578-4123.2US  
Serial No.: 09/348,354  
Filing Date: 7/7/1999  
Title: CHIMAERIC ADENOVIRUSES

**Attorney Docket No.: 2578-4509.2US**

Attorney Docket No.: 2578-4231US  
Serial No.: 09/444,284  
Filing Date: 11/19/1999  
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE  
TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR  
ENDOTHELIAL CELLS

Attorney Docket No.: 2578-3982.2US  
Serial No.: 09/517,898  
Filing Date: 3/3/2000  
Title: MEANS AND METHODS FOR FIBROBLAST-LIKE OR  
MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.: 2578-4038.1US  
Serial No.: 09/549,463  
Filing Date: 4/14/2000  
Title: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL

Attorney Docket No.: 2578-4070.1US  
Serial No.: 09/573,740  
Filing Date: 5/18/2000  
Title: SEROTYPE OF ADENOVIRUS AND USES THEREOF

Attorney Docket No.: 2578-4489US  
Serial No.: 09/665,472  
Filing Date: 9/20/2000  
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE  
TROPISM FOR DENDRITIC CELLS

Attorney Docket No.: 2578-4843US  
Serial No.: 09/843,894  
Filing Date: 4/27/2001  
Title: AAV VECTOR PRODUCTION

Attorney Docket No.: 2578-3840.1US  
Serial No.: 09/900,062  
Filing Date: 7/6/2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT  
ADENOVIRUS TO BE USED IN GENE THERAPY

**Attorney Docket No.: 2578-4509.2US**

Attorney Docket No.: 2578-3833.5US  
Serial No.: 09/918,029  
Filing Date: 7/30/2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT  
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-4509.1US  
Serial No.: 09/928,262  
Filing Date: 8/10/2001  
Title: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY  
FOR PRIMARY HUMAN CHONDROCYTES

Attorney Docket No.: 2578-4123.1US  
Serial No.: 09/953,280  
Filing Date: 9/14/2001  
Title: CHIMAERIC ADENOVIRUSES

Attorney Docket No.: 2578-5148US  
Serial No.: 10/002,750  
Filing Date: 11/15/2001  
Title: COMPLEMENTING CELL LINES

Attorney Docket No.: 2578-5006.1US  
Serial No.: 10/010,645  
Filing Date: 11/13/2001  
Title: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY  
FOR MESENCHYMAL STEM CELLS

Attorney Docket No.: 2578-3833.6US  
Serial No.: 10/038,271  
Filing Date: 10/23/2001  
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT  
ADENOVIRUS TO BE USED IN GENE THERAPY

**Attorney Docket No.: 2578-4509.2US**

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Allen C. Turner', with a long horizontal flourish extending to the right.

Allen C. Turner  
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Date: February 17, 2004  
ACT/bv

Enclosures: Form PTO-1449 or PTO/SB/08  
Cited Documents  
Document in ProLaw

Substitute for form 1449A/PTO

*(use as many sheets as necessary)*

Sheet	1	of	2
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*Complete if Known*

Application Number	To be assigned
Filing Date	February 17, 2004
First Named Inventor	Havenga et al.
Group Art Unit	(presumed) 1635
Examiner Name	(presumed) B. Whiteman
Attorney Docket Number	2578-4509.2US

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	To be assigned
		Filing Date	February 17, 2004
		First Named Inventor	Havenga et al.
		Group Art Unit	(presumed) 1635
		Examiner Name	(presumed) B. Whiteman
Sheet 2 of 2	Attorney Docket Number	2578-4509 211S	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		#VERMA, Nature, 1997, pp. 239-42, Vol. 389.	
		#ANDERSON et al., Nature, 1998, pp. 25-30, Vol. 392.	
		#ARAI et al., J. Rheumatol, 1997, pp. 1787-95, Vol. 24.	
		#DOHERTY et al., Osteoarthritis and Cartilage, 1998, pp. 153-60, Vol. 6.	
		#IKEDA et al., The Journal of Rheumatology, 2000, pp. 990-6, Vol. 27.	
		#NIXON et al., Clinical Orthopaedics and Related Research, 2000, pp. S201-213, Vol. 379S.	
		#ARAI et al., Adenovirus Vector-Mediated Gene Transduction to Chondrocytes: In Vitro Evaluation of Therapeutic Efficacy of Transforming Growth Factor-beta1 and Heat Shock Protein 70 Gene Transduction, Journal of Rheumatology, 1997, pp. 1787-95, Vol. 24, No. 9.	
		#ARAI et al., Control of Delivered Gene Expression in Chondrocytes Using Heat Shock Protein 70B Promoter, Journal of Rheumatology, August 1999, pp. 1769-74, Vol. 26, No. 8.	
		#BARAGI et al., Transplantation of Transduced Chondrocytes Protects Articular Cartilage from Interleukin 1-Induced Extracellular Matrix Degradation, Journal of Clinical Investigation, 1995, pp. 2454-60, Vol. 96, No. 5.	
		#DUPREZ et al., Overexpression of BMP-2 and BMP-4 alters the size and shape of developing skeletal elements in the chick limb, Mechanisms of Development, 1996, pp. 145-57, Vol. 57, No. 2.	
		#SMITH et al., Genetic Enhancement of Matrix Synthesis By Articular Chondrocytes, Arthritis and Rheumatism, May 2000, pp. 1156-64, Vol. 43, No. 5.	

Examiner Signature		Date Considered	
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#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: \_\_\_\_\_

Filed: \_\_\_\_\_

For: \_\_\_\_\_, which application is being relied upon for an earlier filing date under 35

U.S.C. § 120.

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<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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